

1623



PATENT

Attorney Docket No. 12636-263

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application |) | <u>PATENT APPLICATION</u> |
| |) | |
| Inventor(s): Joseph Rubinfeld et al. |) | |
| |) | Confirmation No.: 2253 |
| Application No.: 10/081,974 |) | |
| |) | Art Unit No.: 1623 |
| Filed: February 21, 2002 |) | |
| |) | |
| Title: Sequential Therapy Comprising A 20(S)-Camptothecin And A Pyramidine Base Analog |) | Examiner: Fisher, Latonia |
| |) | |

Mail Stop IDS
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
- (2) It is being filed within 3 months of entry of a national stage
-- OR --
- (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
- (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- a certification as specified in §1.97(e) is provided below; or
- a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; and
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

Fee Authorization. The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 12636-263).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: Nov. 5. 2003

By:


Shirley Chen, Ph.D., Reg. No. 44,608

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CERTIFICATION

(Attachment to Information Disclosure Statement)

- 37 C.F.R. §1.97(e)(1). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- 37 C.F.R. §1.97(e)(2). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing this certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement.

Respectfully submitted,

Dated: Nov. 5, 2003

By:



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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

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| Substitute for form 1449A/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Application No. | 10/081,974 |
| | | | | Filing Date | February 21, 2002 |
| | | | | First Named Inventor | Joseph Rubinfeld |
| | | | | Art Unit | 1623 |
| | | | | Examiner Name | Latonia M. Fisher |
| Sheet | 1 | Of | 2 | Attorney Docket No. | 12636-263 |

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional) 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (10-01)

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| | | | | Art Unit | 1623 |
| | | | | Examiner Name | Latonia M. Fisher |
| Sheet | 2 | Of | 2 | Attorney Docket No. | 12636-263 |
| OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS | | | | | |
| Examiner Initials* | Cite No. ¹ | Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published | | | T ² |
| | | DEVITA, V., et al., Cancer: Principles and Practice of Oncology, (1997) 5 th Edition, pages 335-337. | | | |
| | | LEE, J.H. et al., Antitumor Activity of 7-[2-(N-Isopropylamino)ethyl]-(20S)-Camptothecin, CKD602, as a Potent DNA Topoisomerase I Inhibitor, <i>Arch Pharm Res.</i> (1998), Vol. 21, No. 5, pages 581-589. | | | |
| | | LUZZIO, M.J. et al., Synthesis And Antitumor Acitivity of Novel Water Soluble Derivatives of Camptothecin as Specific Inhibitors of Topoisomerase I, <i>Journal of Medicinal Chemistry</i> (1995), Vol. 38, No. 3, pages 395-401. | | | |
| | | WALL, M.E. et al., Plant Antitumor Agents. 30. ^{1a,b} Synthesis And Structure Activity of Novel Camptothecin Analogs, <i>J Med. Chem.</i> (1993) Vol. 36, No. 18, pages 2689-2700. | | | |
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| EXAMINER SIGNATURE | | | DATE CONSIDERED | | |

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.